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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/659,737	09/11/2000	Miroslav Blumenberg	71369.172 and PFI-024US	5697

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08/13/2003

Charles Ashbrook
Parke Davis
Patent Department
2800 Plymouth Road
Ann Arbor, MI 48105

EXAMINER

MONSHIPOURI, MARYAM

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 08/13/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/659,737

Applicant(s)
Blumenberg et al.

Examiner
Maryam Monshipouri

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1652



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-5, 22, 23, and 25 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3, 4, 22, 23, and 25 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. _____.
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 20
- ☐ Interview Summary (PTO-413) Paper No(s). _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

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Claims 6-21, 24, 26-47 have been canceled. Claims 1-5, 22-23 and 25 are still at issue and are present for examination.

Applicants' arguments filed on 6/5/2003, paper No. 20, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 3-4, 22-23 and 25 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated DNA molecules that are 90% homologous to SEQ ID NO:1 while being able to retain kinase function of MLK4 gene product, does not reasonably provide enablement for any DNA sequence homologous to SEQ ID NO:1, as stated previously. In traversal of this rejection applicant argues that the term "homologous" is clearly defined in the specification in terms of both structure and function. This is because in page 9, lines 13-25, applicant has referred to the function of claimed DNA sequences by reciting and defining the phrase "useful in practicing the invention". According to applicant's definition for said phrase, (i) capability of encoding peptides that can generate antibodies that immunospecifically recognize the MLK4 gene product, (ii) ability to detect MLK4 transcript in a

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test sample, (iii) enabling a method for alteration the expression of endogenous MLK4 gene and (iv) capability of being used to amplify DNA molecules comprising MLK4 ORF in eukaryotic cells are all considered as functions for claimed DNA molecules. Thus, the term "homologous" in view of applicant, has been defined in terms of both structure and function and it is only a matter of routine experimentation for the skilled artisan to determine whether any DNA sequences are homologous to SEQ ID NO:1, according to the teachings in the specification.

With respect to the phrase "substantial portion" applicant argues that the Examiner has mistakenly interpreted a non-limiting embodiment of said term. He/she then continues by stating that in page 10, lines 29-33 a "peptide fragment of a MLK4-related polypeptide refers to a polypeptide consisting of a "subsequence" of SEQ ID NO:2, which is useful in practicing he invention." He/she also provides the same argument as above in support of function for the term "substantial portion" in claims 4-5, relying on the definition of the phrase "useful in practicing the invention" already mentioned above, and finally requests withdrawal of the rejection.

These arguments were fully considered but were found **unpersuasive**. This is because the functions recited for the term "homologous" can be applied an enormous number (genera) of DNA fragments (homologs) such as those having 70% identity to SEQ ID NO:1, many embodiments of which do not necessarily retain the functions applicant recited above. For example, which region in SEQ ID NO:1 homologs is likely to encode peptides which can generate antibodies, that can specifically recognize MLK4 gene product? Which DNA homologs in the claimed genus are more likely to detect MLK4 transcripts in a test sample? What does

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“enabling a method for altering the expression of endogenous MLK4 gene “mean? Which method applicant is referring to? etc.

Since the skilled artisan cannot answer said questions by referring to the disclosure, providing merely **two species** (i.e SEQ ID NO:1 and DNA sequences encoding SEQ ID NO:2) in the specification without further guidance, as is the case here, in contrary to applicants opinion, forces the skilled artisan to go through the burden of undue experimentation in order to screen for DNA homologs that have kinase activity and are within the scope of this invention.

Applicant is reminded that lack of enablement is even more grave with respect to the term “substantial portion” because in this case **both structural and functional information is lacking**. The examiner is not clear as to why applicant is of the opinion that she is focusing a non-limiting embodiment of the invention and what applicant means by the term “subsequence” apart from DNA fragments.

Both sections of page 10, cited by the examiner and by applicant, are basically directed to a genera of fragments of SEQ ID NO:1. As explained previously, many embodiments of DNA sequence consisting of at least 20% of length of SEQ ID NO:1 (see page 10 lines 21-27 of the specification) or of a “subsequence” of SEQ ID NO:1 (which can be of any base length) do not even retain enough number of bases in order to be able to encode a product with kinase function. Applicant is well ware that the kinase catalytic site is usually about 250-300 amino acids in length which requires a base length of at least 750-900 nucleotides. Hence, without further guidance about the structure of “limiting” or “non-limiting” embodiments of DNA molecules of

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claims 4-5, the skilled artisan, once again, has to go through the burden of undue experimentation in order to make the claimed products. The issue of lack of enablement due to absence of kinase function directed to the term "substantial portion" is identical to that elaborated for the term "homologus" and has already been addressed above.

In conclusion, in view of current arguments in addition to tho provided previously the rejection directed to DNA molecules of claims 3-4 is maintained. Since claimed DNA molecules are not enabled, vectors, host cells and methods of expressing said molecules (claims 22-23 and 25) are not enabled either.

3. Claims 3-4, 22, 23, 25 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, according to previous office action. In traversal of this rejection applicant basically provides the same arguments incited above which have already been dealt with. Hence, for reasons set forth above in addition to tho provided in the previous office action, the rejection remains.

Since claimed DNA molecules are inadequately described, vectors, host cells and methods of expressing said molecules (claims 22-23 and 25) are inadequately described as well.

4.

Allowable Subject Matter

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5. Claim 5 is objected to as being dependent upon a rejected base claim 4, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. Claims 1-2 are allowed for the reasons of record.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri Ph.D. whose telephone number is (703) 308-1083. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Dr. P. Achutamurthy, can be reached at (703) 308-3804.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

M. Monshipouri
MARYAM MONSHIPOURI, PH.D.
PRIMARY EXAMINER